EXPRESS MAIL LABEL NO. EV161878130US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Continuation of:

Applicants:

Kelly J. Henrickson, et al.

Serial No.:

09/484,704

Filed:

January 18, 2000

For:

METHOD OF DETECTING THE PRESENCE OF A

TARGET NUCLEIC ACID VIA A MULTIPLEX

AMPLIFICATION REACTION USING UNEQUAL PRIMER

CONCENTRATION

Group Art Unit:

1637

Examiner:

J. Siew

Commissioner For Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.98, enclosed herewith are documents which the Applicants in the above-identified patent application wish to bring to the attention of the Examiner for consideration in connection with the examination on the merits of this patent application.

U.S. Patents

4,683,202; Mullis; July 28, 1987.

5,176,995; Sninsky, et al.; January 5, 1993.

5,187,060; Cerutti, et al.; February 16, 1993.

5,288,630; Wathen; February 22, 1994.

5,508,168; Orle, et al.; April 16, 1996.

5,712,092; Orth, et al.; January 27, 1998.

5,744,299; Henrickson; April 28, 1998.

5,932,222; Randolph, et al.; August 3, 1999.

6,015,664; Henrickson; January 18, 2000.

Foreign Patents

418960A2; EP; 27.03.91.

Non-Patent Documents

Briedis, et al., "Influenza B Virus Genome: Sequences and Structural Organization of RNA Segment 8 and the mRNAs Coding for the NS₁ and NS₂ Proteins," J. Virol. 42(1):186-193 (1982).

Fan, et al., "Rapid Diagnosis of Human Parainfluenza Virus Type 1 Infection by Quantitative Reverse Transcription-PCR-enzyme Hybridization Assay," J. Clin. Microbiol. 34:1914-1917 (1996).

Henrickson, et al., "Antibody Response in Children to Antigen Sites on Human PIV-3 HN: Correlation with Known Epitopes Mapped by Monoclonal Antibodies," Vaccine 8:75-80 (1990).

Henrickson, et al., "Neutralizing Epitopes of Human Parainfluenza Virus Type 3 are Conformational and cannot be Imitated by Synthetic Peptides," <u>Vaccine</u> 9:243-249 (1991).

Henrickson, "Monoclonal Antibodies to Human Parainfluenza Virus Type 1

Detect Major Antigenic Changes in Clinical Isolates," J. Infect. Dis. 164:1128-1134

(1991).

Henrickson, et al., "Genetic Variation and Evolution of Human Parainfluenza Virus Type 1 Hemagglutinin Neuraminidase: Analysis of 12 Clinical Isolates," <u>J. Infect. Dis.</u> 166(5):995-1005 (1992).

Henrickson, "Human Parainfluenza Viruses," In, E.H. Lennette (ed.),
Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections. American
Public Health Association (1993).

Henrickson, et al., "Epidemiology and Cost of Human Parainfluenza Virus Types 1 and 2 Infection in Young Children," Clin. Infect. Dis. 18:770-779 (1994).

Henrickson, et al., "Recovery of Human Parainfluenza Virus Types One and Two," J. Vir. Methods 46:189-206 (1994).

Henrickson, et al., "Two Distinct Human Parainfluenza Virus Type 1 Genotypes Detected during the 1991 Milwaukee Epidemic," J. Clin. Microbiol. 34:695-700 (1996).

Henrickson, et al., "Isolation and Detection Methods Useful for Efficient Recovery of Human Parainfluenza Virus Types One and Two," Clin. Infect. Dis. (submitted).

Karron, et al., "Rapid Detection of Parainfluenza Virus Type 3 RNA in Respiratory Specimens: Use of Reverse Transcription-PCR-enzyme Immunoassay,"

J. Clin. Microbiol. 32:484-488 (1994).

Precious, et al., "Sequence Analysis of the HN Gene of Parainfluenza Virus Type 2," J. Gen. Virol. 71:1163-1168 (1990).

Consideration of these documents during the examination of this application is respectfully requested. As this Statement refers to a related case (09/484,704), no

copies of the references are enclosed. If any fees are necessary to enter this Statement, please charge deposit account 17-0055.

Respectfully submitted,

Kelly J. Henrickson, et al.

January 27, 2004

Jean C. Baker

QUARLES & BRADY LLP 411 East Wisconsin Avenue Milwaukee, WI 53202

Reg. No.: 35,433 (414) 277-5709

Please type a plus sign (+) inside this box -	+	
---	---	--

Sheet 1

PTO/SB/08A (08-00)
Approved for use through 10/31/2002.
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ite for form 1449A/PTC)		Complete if Kn wn		
				Application Number		
INF	ORMATION	DI	SCLOSURE	Filing Date	January 27, 2004	
STATEMENT BY APPLICANT				First Named Inventor	Kelly J. Henrickson	
				Group Art Unit		
	(use as many she	ets a	s necessary)	Examiner Name		
Sheet	1	of	3	Attorney Docket Number	650053.91126	

				U.S. PATENT DOC	JMENTS	
Examiner Initials*	Cite No.1	U.S. Patent Number	Kind Code ²	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,683,202		Mullis	7/28/87	
		5,176,995		Sninsky, et al.	1/5/93	
		5,187,060		Cerutti, et al.	2/16/93	
		5,288,630		Wathen	2/22/94	
		5,508,168		Orle, et al.	4/16/96	
		5,712,092		Orth, et al.	1/27/98	
		5,744,299		Henrickson, et al.	4/28/98	
		5,932,222		Randolph, et al.	8/3/99	
		6,015,664		Henrickson	1/18/00	
		<u> </u>				
		<u> </u>				
			_	_	<u> </u>	
						
			_			
		<u> </u>				
						·

				FOI	REIGN PATENT DOCUMEN	TS		
Examiner Initials*	Cite No.1	Office	Foreign Patent Do 3 Number4	Kind Code (If known)		Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		EΡ	418960	A2	EP	27.03.91		\Box
		-				 		⊬
	_							匚
								\vdash
								\vdash
					}			├

(- ·	
Examiner	Date
Signature	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box ->	\Box	١
, 10000 type a pice a girt / minute minute y	T	ı

us sign (+) inside this box

+

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE work Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for t	form 1449B/PTO		Complete if Known			
			Application Number			
INFOR	MATION [DISCLOSURE	Filing Date	January 27, 2004		
STATE	MENT BY	'APPLICANT	First Named Inventor	Kelly J. Henrickson		
OIAIL		All Liorus	Group Art Unit			
(L	ise as many shee	its as necessary)	Examiner Name			
Sheet 2	of	3	Attorney Docket Number	650053.91126		

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Briedis, et al., "Influenza B Virus Genome: Sequences and Structural Organization of RNA Segment 8 and the mRNAs Coding for the NS1 and NS2 Proteins," J. Virol. 42(1):186-193 (1982).	
		Fan, et al., "Rapid Diagnosis of Human Parainfluenza Virus Type 1 Infection by Quantitative Reverse Transcription-PCR-enzyme Hybridization Assay," J. Clin. Microbiol. 34:1914-1917 (1996).	
		Henrickson, et al., "Antibody Response in Children to Antigen Sites on Human PIV-3 HN: Correlation with Known Epitopes Mapped by Monoclonal Antibodies," Vaccine 8:75-80 (1990).	
		Henrickson, et al., "Neutralizing Epitopes of Human Parainfluenza Virus Type 3 are Conformational and cannot be Imitated by Synthetic Peptides," Vaccine 9:243-249 (1991).	
		Henrickson, "Monoclonal Antibodies to Human Parainfluenza Virus Type 1 Detect Major Antigenic Changes in Clinical Isolates," J. Infect. Dis. 164:1128-1134 (1991).	
		Henrickson, et al., "Genetic Variation and Evolution of Human Parainfluenza Virus Type 1 Hemagglutinin Neuraminidase: Analysis of 12 Clinical Isolates," J. Infect. Dis. 166(5):995-1005 (1992).	
		Henrickson, "Human Parainfluenza Viruses," In, E.H. Lennette (ed.), Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections. American Public Health Association (1993).	
		Henrickson, et al., "Epidemiology and Cost of Human Parainfluenza Virus Types 1 and 2 Infection in Young Children," Clin. Infect. Dis. 18:770-779 (1994).	
		Henrickson, et al., "Recovery of Human Parainfluenza Virus Types One and Two," J. Vir. Methods 46:189-206 (1994).	
		Henrickson, et al., "Two Distinct Human Parainfluenza Virus Type 1 Genotypes Detected during the 1991 Milwaukee Epidemic," J. Clin. MIcrobiol. 34:695-700 (1996).	
		Henrickson, et al., "Isolation and Detection Methods Useful for Efficient Recovery of Human Parainfluenza Virus Types One and Two," Clin. Infect. Dis. (submitted).	

Examiner	Date
Signature	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box ->	+
--	---

Please type a plus sign (+) inside this box

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitu	ute for form 1449B/PT	0		Complete if Known		
				Application Number		
INF	ORMATIOI	N D	ISCLOSURE	Filing Date	January 27, 2004	
STA	TEMENT	RY	APPLICANT	First Named Inventor	Kelly J. Henrickson	
0.7			/	Group Art Unit		
	(use as many s	sheet	s as necessary)	Examiner Name		
Sheet	3	of	3	Attorney Docket Number	650053.91126	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Karron, et al., "Rapid Detection of Parainfluenza Virus Type 3 RNA in Respiratory Specimens: Use of Reverse Transcription-PCR-enzyme Immunoassay," J. Clin. Microbiol. 32:484-488 (1994).	
		Precious, et al., "Sequence Analysis of the HN Gene of Parainfluenza Virus Type 2," J. Gen. Virol. 71:1163-1168 (1990).	
-			
	_		
Examine		Date Considered	

Examiner	Date
Signature	Considered

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.